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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 775,925 | 02 01 2001 | Ralf M. Luche | 200125.420 | 3867 |

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EXAMINER

SAIDHA, TEKCHAND

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 01/21/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|-----------------|----------------|
| Application No. | Applicant(s) |
| 09/775925 | Luche et al. |
| Examiner | Group Art Unit |
| T. Soudha | 1652 |
| | 7 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE — One — MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 10/16/01
This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-98 is/are pending in the application.
Of the above claim(s) is/are withdrawn from consideration.
Claim(s) is/are allowed.
Claim(s) is/are rejected.
Claim(s) is/are objected to.
☒ Claim(s) 1-98 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on is approved disapproved.

The drawing(s) filed on is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number)

received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received:

Attachment(s)

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other

Office Action Summary

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RESTRICTION

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 45-46, drawn to DSP-12 (Dual specificity phosphatase - SEQ ID NO : 2 and mutants), classified in class 435, subclass 194.
 - II. Claims 2-9 & 14, drawn to polynucleotide encoding DSP-12, vector, host cell and method of making the protein, classified in class 435, subclass 194.
 - III. Claims 10-13 & 22-25, drawn to anti-sense strand (coding strand) and method of detecting DSP-12 polypeptide expression, classified in class 435, subclass 6.
 - IV. Claims 15-21, drawn to antibody to DSP-12, composition and method of use, classified in class 424, subclass 130.1
 - V. Claims 26-29, drawn to method of screening an agent that modulates (inhibits/activates) DSP-12 activity, classified in class 435, subclass 69.2.
 - VI. Claims 30-32 & 42, drawn to method of screening an agent that modulates DSP-12 activity [different steps], classified in class 435, subclass 69.2.
 - VII. Claims 33-41, drawn to a method of modulating a proliferative, differentiative and survival response of a cell, classified in class 435, subclass 376 377.
 - VIII. Claims 43-44, drawn to a method of treatment of a patient afflicted with a disorder associated with DSP-12 activity, classified in class 424, subclass 94.5.

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- X. Claims 50 & 94-95, drawn to DSP-13 (Dual specificity phosphatase - SEQ ID NO : 4 or 6 and mutants), classified in class 435, subclass 194.
- XI. Claims 51-58 & 63, drawn to polynucleotide encoding DSP-13, vector, host cell and method of making the protein, classified in class 435, subclass 194.
- XII. Claims 59-62 & 71-74, drawn to anti-sense strand (coding strand) (SEQ ID NO : 5) and method of detecting DSP-13 polypeptide expression, classified in class 435, subclass 6.
- XIII. Claims 64-70, drawn to antibody to DSP-13, composition and method of use, classified in class 424, subclass 130.1
- XIV. Claims 75-78, drawn to method of screening an agent that modulates (inhibits/activates) DSP-13 activity, classified in class 435, subclass 69.2.
- XV. Claims 79-81 & 91, drawn to method of screening an agent that modulates DSP-13 activity [different steps], classified in class 435, subclass 69.2.
- XVI. Claims 82-90, drawn to a method of modulating a proliferative, differentiative and survival response of a cell, classified in class 435, subclass 376 377.
- XVII. Claims 92-93, drawn to a method of treatment of a patient afflicted with a disorder associated with DSP-13 activity, classified in class 424, subclass 94.5.
- XVII. Claims 96-98, drawn to a method of screening a binding molecule of DSP-13,

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3. The nucleic acids of Group II (or DNAs) encoding the DSP-12 of Group I are independent chemical entities and require different searches. They are chemically and biologically distinct molecules. Additionally, the DNA has other functions besides encoding the enzyme. Since the DSP-12 polypeptide and the DNA are biologically and chemically distinct, the manner of using the DNA may not necessarily involve the enzyme. At the minimum, the enzyme can be used to delineate molecular weight parameters in protein gel electrophoresis. The enzyme and DNA have fundamentally different molecular structure, each with its own set of functionality. Enzyme, for example is biologically active, whereas DNA encoding the enzyme, is not. Inventions of Group I and III are distinct for the same reasons as Inventions of Groups I and II.

4. Inventions of Group I and IV are distinct because protein and antibody are chemically and biologically distinct molecules. Antibody and protein have fundamentally different molecular structure, each with its own set of functionality. Antibodies, for example, are formed in the B-cells and are useful for binding to particular residues. Proteins do not function to bind in the particular immunological way that antibodies do, and therefore have different specificities for different substrates, and do not purport to have the kinds of specific activity that antibodies have.

5. Inventions II and IV or III and IV are patentably distinct from each other. The nucleic acids, vectors, cells, and methods of Group I or the anti-sense strand or molecule of Group III and the antibodies and methods of Group IV do not require each other for their practice; have separate

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from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

6. Inventions I & V-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the DSP-12, as claimed in Group I, can be used in a materially different process other than the methods in Group V-IX, such as in the preparation of antibodies. Similarly the polynucleotide of Group II can be used in a materially different process other than developing a method of detection or a method of identifying a compound, or treatment method, etc., of Groups V-IX.

7. The methods of Inventions V-IX are related in that each method requires the use of Invention I or II or III or IV. However, the steps and end points of the methods are wholly different and therefore Inventions V-IX are patentably distinct.

8. Inventions of Groups X-XVIII are drawn to inventions involving DSP-13 and are distinct from Groups I-IX, drawn to inventions involving DSP-12, by virtue of structure and activity. Also inventions of Groups X-XVIII are distinct from among one another for the same reasons as Groups

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9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.


10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Tekchand Saidha
Primary Examiner
Art Unit 1652
January 19, 2003